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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,283	02/14/2002	Matthias Rath	11957/20	3317

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EXAMINER	
MARX, IRENE	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/077,283	RATH, MATTHIAS	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-7 and 10-26* is/are pending in the application.

4a) Of the above claim(s) *4-7,10-22 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 5/31/05 is acknowledged. Claims 1 and 23-25 are being considered on the merits.

Claims 4-7, 10-22 and 26 are withdrawn from consideration as directed to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for the recited amounts "of a daily dosage" as required in new claims 23-25 (See, e.g., Specification, page 6). There is no correlation between the recited ranges and "daily dosage". It is noted that "daily dosage" is an administration limitation which inconsistent with a composition claim.

Moreover, no basis or support is found in the present specification for the composition claimed in claim 25 consisting of certain ingredients. The composition closest to that claimed appears to be disclosed at bridging paragraph between pages 10 and 11. However, the range of Lipoamide is 0.01 - 100 mg and it contains 0.01-10 mg calcium .

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant's amendment does not address the crux of the rejection regarding the limitation of "daily dosage" in a composition claim.

It is also noted again that Table 6 has specific amounts rather than ranges. Also the components in the table do not correspond to any of the claim designated inventions.

Please see *Gentry Gallery v. Berkline* 45 U.S.P.Q.2d 1498 for a discussion related to broadening the claimed invention without support in the as-filed specification. Please see *PurduePharma v. Faulding* 56 U.S.P.Q.2d 1481 for a discussion related to a failure to describe a claimed generic concept in the narrative portion of the specification, but rather basing support on limitations in examples.

Therefore the rejection is deemed proper and it is adhered to.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23-25 are confusing in being directed to a "composition" presumably for oral administration, while as now amended the claims are directed to a combination of at least four of various chemical substances. Compositions generally contain a carrier. In light of the use of the limiting transitional phrase "consisting of" the claim designated invention excludes a carrier.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over The Merck Index taken with Sigma Catalogue. In Merck Index, see, entry 1701, which consists of calcium and citrate; entry 5699 which consists of magnesium and citrate; entry 1688 which consists of calcium and ascorbic acid; In Sigma Catalog, see, e.g. page 772, for a composition consisting of calcium and pantothenic acid or page 950 for a composition consisting of succinate and calcium.

Clearly one of ordinary skill in the art would have been motivated to combine magnesium citrate with calcium succinate and calcium ascorbate and calcium pantothenate, for example, for the expected benefit of treating a calcium related bone deficiency and providing anti-oxidants.

It is noted that the references do not teach that the composition can be used for improving bioenergy metabolism, however, the intended use of the composition does not distinguish the composition since such undisclosed use is intrinsic in the nutritional supplement taught by the references. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does

not create a structural difference, thus, the intended use is not limiting. "The claiming of a new use . . . which is inherently present in the prior art does not necessarily make the claim patentable." *In re Best*, 195 USPQ 430, 433 (CCPA 1977). When applicant claims a "composition in terms of function . . . and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection" (MPEP 2112).

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mothernature.com taken with Whole Health Discount Center. The claim is directed to a composition consisting of four or more chemical substances from a list that includes citrate and calcium.

Mothernature.com teaches compositions which contain thiamine, riboflavin, nicotinic acid, niacinamide and pantothenate, respectively, ascorbate, thiamine, riboflavin (vitamin B-2), niacin, pantothenic acid for oral administration. In addition, Whole Health Discount Center teaches compositions which contain thiamine, riboflavin, nicotinic acid, niacinamide and pantothenate, respectively, thiamine (Vitamin B1), riboflavin (vitamin B-2), niacin (nicotinate), and pantothenic acid for oral administration. It is noted that the references do not teach that the composition can be used specifically for improving bioenergy metabolism, however, it implies the intended use, since it is intended as a dietary supplement. In any event, the intended use of the composition does not distinguish the composition since such undisclosed use is intrinsic in the disclosed composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus, the intended use is not limiting. "The claiming of a new use . . . which is inherently present in the prior art does not necessarily make the claim patentable." *In re Best*, 195 USPQ 430, 433 (CCPA 1977). When applicant claims a "composition in terms of function . . . and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection" (MPEP 2112).

The references differs from the invention as claimed in containing ingredients other than the compounds *per se*. However, the provision of chemical compounds as nutritional supplements such as vitamins is old and well known in the art, and applicant has not

demonstrated that administration of at least four ingredients from a laundry list in any amount as claimed provides unexpected results.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the compositions of Mothernature.com or Whole Health Discount Center, if necessary, by excluding other ingredients, such as PABA and/or choline.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments as they pertain to the above rejections have been fully considered but they are not deemed to be persuasive.

Applicant states that the claims are amended to require at least 5 of the listed components (Response, page 16, line 2). However, the claims of record require four or more. In any event the rejection as now formulated addressed the new limitation added to the claims.

Applicant(s) argue(s) that there is no suggestion or motivation to combine references. However, motivation can come not only from direct teaching of the prior art, but also the nature of the problem to be solved and/or the knowledge of persons of ordinary skill in the art, Ruiz v. A.B. Chance Co. 357 F.3d 1270, 69 USPQ2d 1686 (2004). The cited references are in the same field of endeavour and seek to solve the same problems as the instant application and claims, and one of skill in the art is free to select components available in the prior art, *In re* Winslow, 151 USPQ 48 (CCPA, 1966). Further, the examiner recognizes that references cannot be arbitrarily combined that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references, *In re* Nomiya, 184 USPQ 607 (CCPA 1975). However, there is no requirement that a motivation to make the modification be expressly articulated. One test for combining references is what the combination of dislosures taken as a whole would suggest to one versed in the art, rather than by their specific disclosures, *In re* Bozek, 163 USPQ 545 (CCPA 1969). In this case, the combination of components known in the art, and used for their known art specific properties, in different combinations is considered to be obvious in the absence of evidence to the contrary.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx
Primary Examiner
Art Unit 1651